

Attorney Docket No.: **KBI-0015**
Inventors: **Ranganathan, Natarajan**
Serial No.: **10/689,359**
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REMARKS

Claims 1-10 are pending in the instant application. Claims 1-10 have been rejected. Claims 1, 8 and 9 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §103

Claims 1-5, 7, 9 and 10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,744,134 (Paul; the '134 patent), in view of Cavalier Vesely et al. (U.S. Patent No. 5,716,615; the '615 patent), Brassart et al. (U.S. Patent No. 5,494,664; the '664 patent), and/or Fridman (U.S. Patent No. 3,950,544; the '544 patent). The Examiner suggests that it would have been *prima facie* obvious for one of ordinary skill in the art to use the compositions of the '134 patent for restoring and maintaining gastrointestinal health, but to include in the compositions the beneficial bacteria *S. thermophilus* since it was a known and used bacteria to benefit the gastrointestinal tract, as taught by the '615 patent, the '664 patent and the '544 patent. The Examiner further suggests that although the '134 patent does not teach the claimed amounts of each component of the composition of the present invention, nor wherein the water content is less than about 0.47, it teaches that the composition mixture may be varied and thus it would have been obvious for one of ordinary skill to optimize the water content and the amounts of components, with a reasonable expectation of success. Applicant respectfully disagrees with the Examiner's conclusions regarding the teachings of the prior art references.

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At the outset, in an earnest effort to advance the prosecution and facilitate allowance of the claims, Applicant has amended claims 1, 8 and 9 to recite that the *Streptococcus thermophilus* bacteria of the claimed composition is present at a concentration of from about 5 to 20 billion colony forming units. Support for these amendments to the claims can be found throughout the specification as filed but in particular at page 13, lines 22-28.

The '134 patent (Paul) teaches compositions composed of the beneficial human intestinal microorganisms, lactobacilli and bifidobacteria. See abstract and column 4, lines 21-29. As acknowledged by the Examiner, nowhere does this patent teach or suggest a composition containing *Streptococcus thermophilus*. Moreover, although the patent teaches that the components of the compositions may contain various concentrations, the compositions discussed are always in a powdered form. It is taught that the powdered compositions can be reconstituted in water just prior to consumption. However, nowhere does this patent teach or suggest that the water content of the composition is critical in any way. In contrast, the instant specification teaches explicitly and then claims explicitly that the water content is critical. See for example page 19, lines 11-18 of the specification as filed. Therefore, this reference fails to teach all of the limitations of the amended claims.

Contrary to the Examiner's suggestion, the other cited references (the '615, '644 and '544 patents) fail to overcome the deficiencies in teaching of the '134 patent. The '615 patent teaches compositions consisting of at least two lactic acid bacteria strains. Although *S. thermophilus* is mentioned in the

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'615 patent, nowhere does this patent teach or suggest that *S. thermophilus* is present in a composition at a concentration of 5 to 20 billion colony forming units. In fact, the '615 patent specifically teaches use of a much higher dose, "at least 10¹¹ colony forming units" of bacteria, or at least 100 billion colony forming units. Contrary to the Examiner's assertions regarding the '664 patent, the '664 patent does not mention *S. thermophilus* in its abstract and the only mention of the bacteria is as a component of yogurt. Therefore, contrary to the Examiner's assertions, the '664 patent does not teach or suggest that *S. thermophilus* is a promoter of gastrointestinal health. Instead, the patent teaches that *Bifidobacterium* are promoters of gastrointestinal health. Also contrary to the Examiner's assertions regarding the '544 patent, the '544 patent also fails to teach or suggest that *S. thermophilus* is a promoter of gastrointestinal health. The '544 patent is a patent directed to a method for producing yogurt from soy protein sources. With respect to *S. thermophilus*, the '544 patent teaches only that in the eighth step of the method claimed, a lactic acid culture is added to the sterile soymilk and that examples of bacteria suitable include *S. thermophilus* and *L. bulgaricus*, among others. There is absolutely no discussion in this patent of a composition containing *S. thermophilus* as a way to promote gastrointestinal health, as suggested by the Examiner.

As a result, neither the '544 patent nor the '664 patent would provide one of skill in the art with the motivation or expectation of success that *S. thermophilus* could be added to a composition for promotion of gastrointestinal health and be expected to be effective. Further, the '615 patent, although

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mentioning *S. thermophilus* as a bacteria for promoting gastrointestinal health, teaches that the concentration of the bacteria must be higher than claimed in the instant invention. As a result, none of these three patents would provide one of skill with the teaching sufficient to overcome the deficiencies in teaching of the '134 patent. Additionally, there would be no expectation of success based on the teaching of the '615 patent, which teaches use of higher concentrations of bacteria than are claimed in the present invention. Based on well-established principles of pharmacology and dose-response, one of skill would not expect that lower doses of bacteria would be beneficial even if a higher dose is so suggested. Finally, none of the three patents cited by the Examiner ('615, '664, '544) overcome the deficiency in teaching of the '134 patent with regard to water content. The instant specification clearly teaches that the amount of water is critical, while the patents cited by the Examiner fail to teach or suggest this limitation.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met. MPEP 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all claim limitations. Clearly the reference cited fails to teach or suggest the invention as claimed. None of the patents cited, either alone or when combined, teaches a composition comprising *S. thermophilus* at a concentration of from 5 to 20 billion colony forming units of bacteria. Further, none

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of the cited references teaches a composition which combines components as claimed, including a limited amount of water content, at 0.47. Therefore, the combination of references cited also fails to provide one of skill in the art with a motivation or an expectation of success, especially when the art cited by the Examiner teaches use of higher amounts of bacteria and fails to teach the critical nature of the water content. Accordingly, it is respectfully requested that this rejection be withdrawn.

Claims 1-10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the '134 patent, in view of the '615 patent, the '664 patent, and/or the '544 patent, and further in view of Halpin-Dohnalek (U.S. Patent No. 5,902,578; the '578 patent). The Examiner suggests that it would have been *prima facie* obvious for one of ordinary skill in the art to alter the composition of the '134 patent, adding *S. thermophilus* as taught by the '615, '664, and '544 patents, and then further modify the composition to include minerals and vitamins. The Examiner suggests that although none of the references teaches all the ingredients in a single composition in the claimed amounts with the claimed water activity, it would have been obvious to do so. Applicant respectfully disagrees with the Examiner's conclusions regarding this combination of references.

As discussed *supra*, Applicant has amended claims 1, 8 and 9 to recite that the compositions of the instant invention contain from 5 to 20 colony forming units of *S. thermophilus* bacteria. Also as discussed *supra*, the combination of the '134 patent with the '615, '664 and '544 patents fails to teach or suggest the limitations of the claims as amended, in particular the dose of bacteria and the amount of water in the claimed composition.

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In this rejection, the Examiner has added the '578 patent to the rejection. The '578 patent teaches compositions for prevention of diarrhea that comprise probiotic bacteria at a dose of at least 10^6 colony forming units (1 million) of each probiotic bacteria in the composition each day. The compositions taught always contain at least three bacteria and the strains are *L. reuteri*, *L. acidophilus*, and *B. infantis*. In contrast, the present disclosure teaches that *Streptococcus thermophilus* advantageously survives and utilizes or degrades urea at pH ranges of between 5 and 6.5, as typically found in the small intestine. This is of benefit to individuals that have or are prone to the accumulation of toxic nitrogenous waste products, and thus is useful for promoting gastrointestinal health. Nowhere does the '578 patent teach or suggest the use of *S. thermophilus*, at any dose, nor does it teach or suggest that water activity must be in the range of 0.47. Therefore, the '578 patent fails to overcome the deficiencies in teaching of the other patents either alone or when combined (the '134 patent, the '615 patent, the '664 patent, and the '544 patent).

In order to establish a *prima facie* case of obviousness, three basic criteria must be met. MPEP 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all claim limitations. Clearly the reference cited fails to teach or suggest the invention as claimed. None of the patents cited, either alone or when combined, teaches a

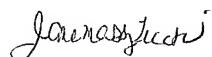
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composition comprising *S. thermophilus* at a concentration of from 5 to 20 billion colony forming units of bacteria. Further, none of the cited reference teaches a composition which combines components as claimed, including a limited amount of water content, at 0.47. Therefore, the combination of references cited also fails to provide one of skill in the art with a motivation or an expectation of success, especially when the art cited by the Examiner teaches use of higher amounts of bacteria and fails to teach the critical nature of the water content. Accordingly, it is respectfully requested that this rejection be withdrawn.

II. Conclusion

The Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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